DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

93546d

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

September 24, 2002

WARNING LETTER

NWE-34-02W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brian Norder
Project Director
Vermont Food Venture Center
1126 Main Street
Fairfax, VT 05454

Dear Mr. Norder:

The U.S. Food and Drug Administration (FDA) conducted an inspection on April 2 and 3, 2002 of your facility, the Vermont Food Venture Center (VFVC), located at 1126 Main Street, Fairfax, VT 05454. VFVC manufactures, packages, and labels a dietary supplement, [redacted], for [redacted]. Labeling for this product was collected and a review of that labeling indicates violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act along with the food, drug, and dietary supplement labeling regulations[1] on the Internet through links on FDA's web page www.fda.gov.

The following violations were noted—

1) This product is misbranded within the meaning of Sections 403(s)(2)(B) and 403(i)(1) of the Act in that its labeling fails to identify the product by using the term "dietary supplement". 21 CFR 101.3(g) permits the word "dietary" to be deleted, provided it is replaced by the name of the dietary ingredients in the product or an

[1] Regulations contain specific provisions, which are intended to implement the Act. Labeling regulations for foods and dietary supplements are set forth in Title 21 Code of Federal Regulations (CFR) Part 101.

appropriately descriptive term indicating the type of dietary ingredients that are in the product.

2) This product is misbranded within the meaning of Section 403(q)(5)(F) of the Act and 21 CFR 101.36, the regulation implementing this provision of the Act. Specifically, the labeling for this product does not contain a "Supplement Facts" panel with the nutrition information required under 21 CFR 101.36.

3) The product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears the unauthorized nutrient content claims "highest potency" and "...many times more potent than...." Under 21 CFR 101.54(f), the claim "high potency" may be used only for vitamins or minerals that are present at 100 percent or more of the Reference Daily Intake (RDI). [redacted] does not meet these requirements because it is not a vitamin or mineral and has no RDI. The product's claims about the potency of [redacted] misbrand the product because they are not authorized by FDA regulation or on the basis of an authoritative statement under section 403(r)(2)(G)(i) of the Act.

This letter is not intended to be an all-inclusive list of the deficiencies in the labeling for this product. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. You should review the labeling for all products manufactured at your facility to assure that they are in compliance. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize violative products and/or enjoin your firm from operating. Pertinent sections of the Act and the regulations are enclosed for your review.

You should notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of revised labels should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for the delay and the time at which the corrections will be completed.

You should direct your reply to Mark Lookabaugh, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any questions concerning this matter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,

Gail T. Costello
Director
New England District Office